



UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Lin Zhi *et al.* Art Unit : Unknown
Serial No. : 10/566,569 Examiner : Unknown
Filed : January 31, 2006 Cust. No. : 20985
Conf. No. : 6058
Title : 6-CYCLOAMINO-2-QUINOLINONE DERIVATIVES AS ANDROGEN
RECEPTOR MODULATOR COMPOUNDS

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are an Information Disclosure Statement, Forms PTO-1449 (6 pages), cited non U.S. patent references, and a return postcard for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

- ☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Dated: July 11, 2006

Attorney Docket No. 18202-030US1/ 1111US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|------------|--|-----------|-----------|
| Applicant | : Lin Zhi <i>et al.</i> | Art Unit | : Unknown |
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P.O. Box 1450
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**INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE
WITH 37 C.F.R. §§ 1.97-1.98**

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (6 pages) and copies of the cited non U.S. Patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item CJ (WO 01/27086) is in the Japanese language and is supplied with a Derwent abstract (item DM). Item CM (WO 02/22585) is in the Japanese language and an English language equivalent is listed (item AI). Item CV (DE 2334738) is in the German language and is supplied with a Derwent abstract (item DK). Item CW (DE 3810706) is in the German language and is supplied with a Derwent abstract (item DL) and a certified translation (item DH). Item CS (EP 0542609) is in the French language and is supplied with a Derwent abstract (item DJ). Item CF (WO 00/66680) is in the German language and an English language equivalent is listed (item CA). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S. and International Applications that have one or more common inventors and/or are commonly owned:

| Docket No. | U.S.S.N. | Filed | Publ. No. |
|-------------------|-----------------|--------------|------------------|
| 002007/1002F | 08/141,246 | 10/22/93 | n/a |
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| 020002/1088B | 11/411,676 | 04/25/06 | n/a |
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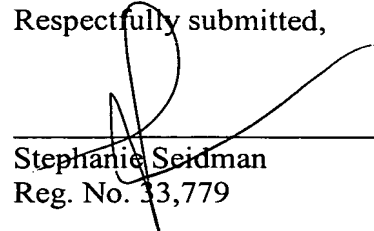
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references or information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g and h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant : Lin Zhi et al.
Serial No. : 10/566,569
Filed : January 31, 2006

Attorney's Docket No.: 18202-030US1/ 1111US
Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,



Stephanie Seidman
Reg. No. 33,779

Dated: July 11, 2006
Attorney Docket No. 18202-030US1/ 1111US
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Sheet 1 of 6

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|---|--|--|-------------------------------|
| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 18202-030US1/1111US | Application No. 10/566,569 |
| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | Applicant Lin Zhi et al. | |
| | | Filing Date January 31, 2006 | |

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| Examiner Initial | Desig. ID | Document Number | Publication Date | Patentee | Class | Subclass | Filing Date If Appropriate |
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| Examiner Signature | Date Considered |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

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| Substitute Form PTO-1449 (Modified) List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | U.S. Department of Commerce Patent and Trademark Office | | Attorney's Docket No. 18202-030US1/1111US | Application No. 10/566,569 |
| | Applicant Lin Zhi et al. | | | |
| | Filing Date January 31, 2006 | | Group Art Unit | |

U.S. Patent Documents

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| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | | | Applicant Lin Zhi et al. | | | | |
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| Foreign Patent Documents or Published Foreign Patent Applications | | | | | | | | |
| Examiner Initial | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation | |
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| | DC | 99/58486 | 11/18/1999 | PCT | | | | |

X*= An English language abstract is provided

X+= An English language equivalent is provided

| Other Documents (include Author, Title, Date, and Place of Publication) | | |
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| | DF | Berger et al., "Interaction of glucocorticoid analogues with the human glucocorticoid receptor," J. Steroid Biochem. Mol. Biol., 41: 733-738 (1992) |
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| | DK | Derwert citing German patent DE 2334738 published 1/1/1975, for: "Hair-dyestuff for oxidation-dyeing process-contg. 4 hydroxy-quinolone-2-derivs. as coupling components." |
| | DL | Derwert citing German patent, DE 3810706 published 10/05/1989, for: "New coumarin derivs. contg. imide gp.- useful as selective herbicides." |
| | DM | Derwert citing Japanese patent WO 01/27086 published 4/19/2001, for: "New tetrahydroquinoline derivatives useful as androgen receptor binding agents for treating e.g. males sexual dysfunction." |
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| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | Applicant Lin Zhi et al. | |
| | | Filing Date January 31, 2006 | Group Art Unit |

Other Documents (include Author, Title, Date, and Place of Publication)

| Examiner Initial | Desig. ID | Document |
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| | DQ | Edwards, et al., "Preparation, Resolution, and Biological Evaluation of 5-Aryl-1,2-dihydro-5H-chromeno[3,4-f]quinolines: Potent, Orally Active, Nonsteroidal Progesterone Receptor Agonists," <i>Journal of Medicinal Chem.</i> 41:2779-85 (1998). |
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| | DS | Fingl et al. "The Pharmacological Basis of Therapeutics", Ch.1 p.1 (1975) |
| | DT | Hamann, et al, "Discovery of a potent, orally active, nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6- (trifluoromethyl)-8-pyridono[5,6-g]- quinoline (LG121071)" <i>J Med Chem.</i> , 42(2):210-2 (1999) |
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| | DV | Hamann, et al., "Nonsteroidal progesterone receptor antagonists based on a conformationally-restricted subseries of 6-aryl-1,2-dihydro-2,2,4-trimethylquinolines," <i>Bioorg Med Chem Lett.</i> , 8(19)2731-6(1998) |
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| | DY | Labrie, et al., "Science behind total androgen blockade: from gene to combination therapy," <i>Clin. Invest. Med.</i> , 16: 475-492 (1993) |
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| | EE | Pathirana et al., "Nonsteroidal human progesterone receptor modulators from the marine alga <i>Cymopolia barbata</i> ," <i>Mol. Pharm.</i> 47:630-635 (1995) |
| | EF | Pooley, et al., "Discovery and preliminary SAR studies of a novel, nonsteroidal progesterone receptor antagonist pharmacophore,," <i>J. Med. Chem.</i> , 41(18): 3461-3466 (1998) |
| | EG | Rodbard, "Mathematics and statistics of ligand assays: an illustrated guide" In: J. Langon and J. J. Clapp, eds., <i>Ligand Assay</i> , Masson Publishing U.S.A., Inc., New York, pp. 45-99, (1981) |
| | EH | Rosen, and Negro-Vilar, "Novel, non-steroidal, selective androgen receptor modulators (SARMs) with anabolic activity in bone and muscle and improved safety profile," <i>Journal of Musculoskeletal Neuronal Interactions/Journal of Musculoskeletal Neuronal Interactions</i> , 2(3):222-224 (2002) |

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| Examiner Signature | Date Considered |
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| Substitute Form PTO-1449 (Modified) | | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 18202-030US1/1111US | Application No. 10/566,569 |
|---|--------------|--|--|-------------------------------|
| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | | Applicant Lin Zhi et al. | |
| | | | Filing Date January 31, 2006 | Group Art Unit |
| Other Documents (include Author, Title, Date, and Place of Publication) | | | | |
| Examiner Initial | Desig. ID | Document | | |
| | EI | Rosen, et al., "Intracellular receptors and signal transducers and activators of transcription superfamilies - novel targets for small-molecule drug discovery," Journal of Medicinal Chemistry 38:25;4855-4874 (1995) | | |
| | EJ | Simental, et al., Transcriptional Activation and Nuclear Targeting Signals of the Human Androgen Receptor, J Biol Chem., 266(1):510-518 (1991). | | |
| | EK | Singh et al., "Androgen receptor antagonists (antiandrogens): structure-activity relationships," Curr. Med. Chem. 7(2): 211-247 (2000) | | |
| | EL | Tacke & Zilch, "Sila-substitution — a useful strategy for drug design?" Endeavour, New Series, 10(4):191-197 (1986); | | |
| | EM | Tegley, et al., "5-Benzylidene 1,2-dihydrochromeno[3,4-f]quinolines, a novel class of nonsteroidal human progesterone receptor agonists," J Med Chem., 41(22):4354-9 (1998) | | |
| | EN | Walsh, et al., "Inhibition of extratesticular stimuli to prostatic growth in the castrated rat by antiandrogens," Endocrinology 86: 624 (1970) | | |
| | EO | Wen, D. X. and McDonnell, D. P. Advances in our understanding of ligand-activated nuclear receptors Current Opinion in Biotechnology 6(5):582-589 (1995) | | |
| | EP | Yin, et al., "Key structural features of nonsteroidal ligands for binding and activation of the androgen receptor," Molecular Pharmacology, 63(1): 211-223 (2003) | | |
| | EQ | Zhi et al. "Nonsteroidal progesterone receptor antagonists based on 6-thiophenehydroquinolines," Bioorg Med Chem Lett., 10(5)415-418 (2000) | | |
| | ER | Zhi, et al., "5-Aryl-1,2,3,4-tetrahydrochromeno[3,4-f]quinolin-3-ones as a novel class of nonsteroidal progesterone receptor agonists effect of A-ring modification," J Med Chem., 42(8)1466-72.(1999) | | |
| | ES | Zhi, et al., "5-Aryl-1,2-dihydrochromeno [3,4-f]quinolines: A Novel Class of Nonsteroidal Human Progesterone Receptor Agonists," Journal of Medicinal Chem. 41:291-302 (1998). | | |
| | ET | Zhi, et al., "Switching androgen receptor antagonists to agonists by modifying C-ringsubstituents on piperidino[3,2-g]quinolinone," Bioorg Med Chem Lett., 9(7)1009-12.(1999) | | |
| | EU | Zhi, L. and Martinborough, E. Chapter 17. Selective androgen receptor modulators (SARMs) Annual Reports in Medicinal Chemistry, 36:169-180 (2001) | | |

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